REMARKS

In the Office Action mailed December 1, 2003:

Applicants' Declaration filed on 9/8/03 under 37 CFR 1.131 was found ineffective to overcome the Gartstein et al. reference in that the Declaration was not signed as required. Applicants apologize for the lack of a properly signed Declaration; such a signed declaration is submitted herewith.

Claims 24-26 and 30-36 were rejected under 35 U.S.C. 102(b) as being anticipated by Pisano et al.(U.S. Patent 5,928,207).

Claims 24, 25, 30-32 were rejected under 35 U.S.C. 102(e) as being anticipated by Gartstein et al.(U.S. Patent 6,379,324).

Claims 27-29 and 37-41 were rejected under 35 U.S.C. 103(a) as being unpatentable over Pisano et al. in view of Lin et al. (U.S. Patent 5,591,139).

Pisano et al.'s lancet has a straight, narrow shaft with parallel sides extending at right angles from a base. When an isotropic etch is used, Pisano et al.'s lancet has an elongated, very thin tip converging to a near infinitesimally small point. Thus the shaft thickness near its tip has a thickness of only a few millimeters. The isotropic etch removes silicon at the same rate in all directions, and continues until the etch stop (the insulating layer of the silicon-on-insulator [SOI] wafer) is reached. This acid etch method is very difficult to control and places severe limitations on the geometry of the lancet tip. The lancet tip is very fragile because of the extreme thinness at its edges and point, as can be seen in FIG. 4. To counter this fragility, Pisano et al. disclose the use of a mixed isotropic/anisotropic etching process. This produces a less elongated tip, but one which has abrupt transitions and is therefore abrasive and more painful for the user.

Pisano et al utilize SOI wafers in all but two of their examples, and consider the use of such wafers advantageous (Col. 5, lines 12-15). SOI wafers consist of two silicon wafers – a device wafer and a handle wafer – bonded together by an insulating layer. Pisano et al. discuss the benefits of using an SOI wafer for their process: the thin device wafer is used to set the lancet thickness, the handle wafer permits normal handling during processing, and the

insulating layer serves as an etch stop for the acid isotropic etch. However, SOI wafers are substantially more expensive than standard silicon wafers, and would be prohibitive for manufacturing operations. Of the two examples not using SOI wafers, one uses a nonstandard thin wafer having a thickness of only 100 micrometers. which would be impractically difficult to handle during processing because it is so thin. The second example, which uses a standard thickness wafer, does not show the geometry of the finished tip nor specifically describe the tip etching process. However, with a standard thickness wafer, double sided etching removes the entire bottom of the wafer under the lancet probe and tip as shown in FIG. 15(l-m) . As a result, no bottom etch stop remains to control the geometry of the bottom of the lancet tip. The lancet tip is acid etched from both sides, resulting in a very fragile poorly-controlled tip geometry. Further, the bottom of the lancet shank comprises a thin ridge.

Applicants' microlancet has been designed to provide increased strength and optimal shaping such that it can penetrate skin reliably and virtually painlessly. As shown in FIG 3A, the probe shape forms a smooth continuous profile without weak spots (page 4, lines 5-9). The penetration portion tapers in its width dimension to form a sharp point at the penetration end. The thickness dimension of the penetration portion may extend from about 50 micrometers to about 250 micrometers. As shown in FIG 1 (G-I) and FIG 3 (B-C), to maintain probe strength, the thickness dimension does not decrease below this thickness range at the penetration end. For a lancet of applicants' design, the force required to puncture the skin is minimal compared to the force required to break the probe (page 4, lines 11-16). A pain perception clinical trial indicated that 15% of patients tested could not even feel the probe penetration using a 100 micrometer thick microlancet, and an additional 58% found the penetration barely noticeable (page 3 lines 13-21). A "sharper" thinner lancet point is therefore unnecessary for relatively painless lancing, but would decrease probe strength.

Applicant's microlancet can be fabricated from any suitable silicon substrate, including standard thickness silicon wafers, and retains the full substrate thickness in the base end for ease of handling and use. The penetration end is thinned to the desired thickness, minimizing tissue displacement and therefore pain.

Pisano et al.'s lancet does not provide a smooth continuous profile, in that the right angles formed between the lancet shaft and the base end (FIG. 1) create weak spots. Pisano et al.'s lancet tip either converges to a extremely thin point (FIG. 4) or contains multifaceted, abrasive transitions (FIG. 7). Neither of the processes disclosed by Pisano et al. for tip formation can be used to fabricate a tip of the design disclosed by applicants wherein a probe

thickness of at least about 50 micrometers is retained at the penetration point in order to maintain probe strength. Nor do Pisano et al's processes permit the thickness of the base and the thickness and shape of the penetration portion to be independently chosen in order to provide a thick basc for ease of handling and a thinned penetration portion with smooth continuous profile to increase strength while minimizing tissue damage. Applicant's microlancet is therefore not anticipated by Pisano et al.

Specifically, claim 24 is believed patentable over Pisano et al. in specifying a penetration portion that extends laterally from the base of the silicon substrate and terminates in a sharp point with a continuous cutting profile. Dependent claims 25-27 and 31-34 are believed patentable for the same reason claim 24 is patentable.

Independent claim 36 is believed patentable for the same reasons claim 24 is patentable and for the additional reason that it specifies that the penetration portion tapers from the base portion toward the point. Dependent claims 37, 42 and 43 are believed patentable for the same reason claim 36 is patentable.

Independent claim 38 is believe patentable because it specifies that the penetration portion has a smooth continuous profile. Dependent claims 39-41 are believed patentable for the same reason claim38 is patentable.

In view of the foregoing, applicants believe that all of the claims are now in condition for allowance and respectfully request the Examiner to pass the subject application to issue. If for any reason the Examiner believes any of the claims are not in condition for allowance, he is encouraged to phone the undersigned at (650) 849-7777 so that any remaining issues may be resolved.

Aside for the fees for Petition to Extend Time, no additional fee is believed due for filing this response. However, if a fee is due, please charge such fee to Morgan, Lewis & Bockius LLP's Deposit Account No. 50-0310.

Respectfully submitted,

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